

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)

MDL No. 2419

Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

Suits Identified in the Attached Exhibits)

**Reply of the Tennessee Clinic Defendants to
the PSC's Response to the Tennessee Clinic Defendants'
Motion to Dismiss for Failure to Comply with Tenn. Code Ann. § 29-26-121**

Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"), Howell Allen Clinic, a Professional Corporation ("Howell Allen"), John W. Culclasure, MD ("Dr. Culclasure"), Debra V. Schamberg, RN ("Ms. Schamberg"), Specialty Surgery Center, Crossville, PLLC ("SSC"), Kenneth R. Lister, MD ("Dr. Lister"), and Kenneth Lister, MD, PC ("Dr. Lister's Practice") (collectively "the Tennessee Clinic Defendants") file this Reply to the Plaintiffs' Steering Committee's ("PSC") Response to the Tennessee Clinic Defendants' Motion to Dismiss for Failure to Comply with Tenn. Code Ann. § 29-26-121.¹

¹ The original Motion to Dismiss is at Dkt. 770. The Tennessee Clinic Defendants' Memorandum of Law in support of the Motion is at Dkt. 898. The PSC's Response is at Dkt. 1116. The PSC filed a separate Response to the Saint Thomas Entities' Motion to Dismiss for Failure to Comply with Tenn. Code Ann. § 29-26-121 and § 29-26-122 at Dkt. 1115. Due to the substantial overlap between the Responses, this Reply addresses both Dkt. 1115 and Dkt. 1116.

Introduction

As this Court likely knows by now, Tenn. Code Ann. § 29-26-121 requires that plaintiffs filing health care liability actions against health care providers in Tennessee serve a presuit notice of intent at least 60 days before filing suit, designed to allow potential defendant health care providers to investigate the claim presuit. Tenn. Code Ann. § 29-26-122 requires that plaintiffs file with the complaint a certificate of good faith certifying an expert has reviewed the case before filing and deemed it meritorious.

The Tennessee Clinic Defendants and the Saint Thomas Entities² have filed Motions to Dismiss, seeking dismissal of various Plaintiffs' complaints for failure to comply with Tenn. Code Ann. § 29-26-121 and § 29-26-122.

After extensive negotiation, the Tennessee Clinic Defendants and the Saint Thomas Entities agreed with the PSC to limit briefing to three specific issues that the Court can address globally:

1. Whether Tenn. Code Ann. § 29-26-122 requires that a plaintiff filing complaints alleging only claims styled as product liability claims file a certificate of good faith with the original complaint.
2. Whether plaintiffs were required to (a) identify Barry Cadden, NECC, and other affiliated parties in the notice of intent to the clinic defendants as health care providers that would be named defendants and (b) provide a HIPAA release allowing clinic defendants to obtain records presuit from Barry Cadden, NECC, and other affiliated defendants pursuant to Tenn. Code Ann. § 29-26-121; and
3. Whether the presuit requirements set forth in Tenn. Code Ann. § 29-26-121 apply to plaintiffs filing complaints alleging only claims styled as product liability claims and, if so, whether the failure to comply with such presuit requirements can be cured by a pleading amendment.

² Saint Thomas West Hospital f/k/a Saint Thomas Hospital, Saint Thomas Health, and Saint Thomas Network.

In this Reply, the Defendants address only issues 1 and 2. Issues 1 and 3 invoke the same legal analysis, *i.e.*, whether plaintiffs attempting to allege “products-only” claims must comply with -121 and -122. Re-analyzing issue 3 adds little.³

For the 43 suits to which issue 1 applies,⁴ the Court must first decide whether Tennessee’s Health Care Liability Act (“HCLA”) truly means what it says. The Act applies to “any civil action...alleging that a health care provider...caused an injury related to the provision of...health care services...regardless of the theory of liability asserted.”⁵ The Tennessee Clinic Defendants respectfully submit that this Court must follow the plain language of the statute to effectuate the intent of the legislature and apply the HCLA to these 43 complaints, regardless of the Plaintiffs’ attempt to circumvent the requirements of the statute by styling their claims as “products only.”

Assuming the Court follows the plain language of the statute’s definitional section, the Court must apply the HCLA’s requirements to these 43 complaints. This requires the Court to decide whether the Plaintiffs were required to file a “certificate of good faith” with their complaints as required by Tenn. Code Ann. § 29-26-122. The remedy for the failure to file a certificate of good faith with the original complaint is dismissal with prejudice pursuant to § 29-26-122(c).

Put simply: (1) The HCLA applies to these 43 cases; and, (2) because these Plaintiffs did not file certificates of good faith, these cases should be dismissed with prejudice.

³ The Plaintiffs in their Response unilaterally injected a fourth issue into the *agreed-upon* list of issues. These Defendants will not waste the Court’s time arguing that issue, as it was not one of the three issues the parties agreed to brief at this point.

⁴ Suits identified in Exhibits 1, 2, and 3.

⁵ TENN. CODE ANN. § 29-26-101(a)(1).

For the 108 suits subject to issue 2,⁶ there is no dispute that the HCLA applies. The Plaintiffs in those suits alleged negligent actions by health care providers that caused injury to patients, clearly within the Act's definition of a "health care liability action." With these cases, the Court must only decide *how* to apply the HCLA's requirement that plaintiffs send presuit notice to health care providers 60 days before filing suit and identify in the notice other health care providers who will be named as defendants.⁷

Because NECC and various Affiliated Defendants are health care providers and are named as defendants, the Plaintiffs were required to identify them in the presuit notices sent to the Tennessee Clinic Defendants. The failure to do so mandates dismissal.⁸

Law and Argument

I. A plaintiff filing a health care liability action must file a certificate of good faith with the complaint.

Prior to filing a "health care liability action," a plaintiff must obtain a signed written statement from a competent expert attesting that there is a good faith basis to maintain the action.⁹ The plaintiff must then file *with the complaint* a "certificate of good faith" certifying that the plaintiff has obtained the required expert statement.¹⁰ Failure to file the certificate renders the suit subject to dismissal *with prejudice*.¹¹ Here, 43 Plaintiffs simply failed to file the required certificate of good faith with their original complaint.

⁶ Suits identified in Exhibit 4.

⁷ TENN. CODE ANN. § 29-26-121.

⁸ *Stevens v. Hickman Comm. Health Care Serv.*, 418 S.W.3d 547, 560 (Tenn. 2013) (holding that dismissal is proper remedy for failure to comply with § 29-26-121).

⁹ TENN. CODE ANN. § 29-26-122(a).

¹⁰ *Id.*

¹¹ TENN. CODE ANN. § 29-26-122(c).

The PSC argues that (1) the complaints at issue alleged product liability, not health care liability, and (2) even if the Court finds that the Plaintiffs' product liability claims are subject to the HCLA, no certificate of good faith was required. Both of these arguments ignore the plain language of the statute.

A. The HCLA applies to the Plaintiffs' complaints, even those trying to allege only product liability claims.

The threshold question the Court must answer is whether the HCLA governs the Plaintiffs' claims. If the HCLA applies to these 43 complaints, the HCLA's certificate of good faith requirement also applies.

The HCLA defines a "health care liability action" as:

any civil action...alleging that a health care provider or providers have caused an injury **related to** the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.¹²

The PSC argues that these Plaintiffs filed complaints against the Tennessee Clinic Defendants that alleged only product liability claims under Tennessee's Product Liability Act ("PLA"), thus absolving them from the HCLA's requirements.¹³ The PSC argues that these "product liability" claims do not implicate the HCLA because the HCLA only applies to claims "arising from the provision of health care services, not the sale or distribution of goods or products."¹⁴

¹² TENN. CODE ANN. § 29-26-101(a)(1) (emphasis added); *Cunningham v. Williamson Cnty. Hosp. Dist.*, 405 S.W.3d 41, 45, n.1, n. 2 (Tenn. 2013) (recognizing change in statutory language from "medical malpractice" to "health care liability").

¹³ This Reply does not address the question of whether, under any reasonable reading of the factual allegations, the Plaintiffs can expand the law to even maintain a product liability action against the Tennessee Clinic Defendants. That question is addressed in the Tennessee Clinic Defendants' Global Motion to Dismiss at Dkt. 771.

¹⁴ Dkt. 1115, p. 13 (emphasis added).

The PSC cites several cases that it contends support the notion that the PLA, not the HCLA, applies to these complaints.¹⁵ Not surprisingly, the cases cited by the PSC are all suits *against drug manufacturers*.¹⁶ Obviously, suits against drug manufacturers for product liability generally proceed under the PLA, not the HCLA.

However, the PSC glosses over the obvious. Here, the Plaintiffs did not sue a drug manufacturer for product liability. They sued *their health care providers for injuries related to health care*. They cannot do so yet sidestep the HCLA.

The PSC's position requires the Court to twice ignore the plain language of the HCLA.

First, its argument that the HCLA applies only to claims "arising from" health care services rewrites the statute. The HCLA does not say "arising from." The Act uses the broader language "**related to**" the provision of health care services.¹⁷

Second, the PSC argues that the definition of "health care services" does not include the administration of medication, characterizing the administration of medication as a "sale" or "distribution" of the medication. This again ignores the plain language of the HCLA, which defines "health care services" as care by health care providers, specifically including physicians and nurses.¹⁸ Additionally, Tennessee courts have consistently held that suits alleging injury related to the administration of medication are

¹⁵ Dkt. 1115, p. 7, nn. 12-13.

¹⁶ Wyeth Pharmaceuticals, Eli Lilly & Co., Novartis, Upjohn Co. (now part of Pfizer), Ciba-Giegy Corp. (now part of Novartis), and Lederle Laboratories (purchased by Wyeth before going out of business in 2008).

¹⁷ TENN. CODE ANN. § 29-26-101(a)(1) (emphasis added).

¹⁸ TENN. CODE ANN. § 29-26-101(b).

governed by Tennessee's Medical Malpractice Act, the *less* expansive precursor to the HCLA.¹⁹

There is no reasonable reading of the complaints or application of Tennessee law that could lead to a finding that the administration of medication is not a health care service. But, even if the Court finds that the administration of medication is not a health care service, there were dozens of other health care services provided by the Tennessee Clinic Defendants to which the Plaintiffs' injuries are indisputably "related." For example, the Plaintiffs' injuries are certainly related to the professional services of the physician performing the procedure, and the PSC concedes that these are health care services in its Opposition to the Tennessee Clinic Defendants' Global Motion to Dismiss.²⁰

The Court must examine the gravamen of the complaint to determine the governing statute.²¹ The factual allegations of the complaint, not the designation chosen by the plaintiff,²² and the predominant aspect of the transaction²³ dictate the applicable substantive law.

¹⁹ See, e.g., *Sharkey v. O'Toole*, No. M2009-0112-COA-R3-CV, 2010 WL 3293925, at *1-*6 (Tenn. Ct. App. Aug. 19, 2010) (analyzing case in which the physician allegedly prescribed Haldol to a patient with a known Haldol allergy as medical malpractice case); *Taylor v. Jackson-Madison Cnty. Gen. Hosp. Dist.*, No. W2005-02471-COA-R3-CV, 2006 WL 2423456, at *1 (Tenn. Ct. App. Aug. 23, 2006) (analyzing case of allegedly negligent use of antibiotic, causing allergic reaction, as medical malpractice case); *Foster v. St. Joseph Hosp.*, No. W2003-00522-COA-R3, 2004 WL 1717679, at *1 (Tenn. Ct. App. July 30, 2004) (characterizing claim that defendant health care providers gave medication to patient to which she was allergic as claim for medical malpractice); *Howse v. State*, 994 S.W.2d 140, 140-41 (Tenn. Ct. App. 1999) (analyzing case of allegedly negligent administration of earwax medication, causing allergic reaction, as medical malpractice case); *Crowe v. Craig*, No. 02A01-9612-CV-00297, 1997 WL 359261, at *1-*6 (Tenn. Ct. App. June 27, 1997) (analyzing case of allegedly negligent administration of pain medication to patient with allergy to pain medication as medical malpractice case); *Oaks v. State*, No. 03-A01-9104BC00129, 1991 WL 260668, at *1 (Tenn. Ct. App. Dec. 12, 1991) ("[t]his is a medical malpractice suit..."; "By way of preface, we note that it was the Oakses' theory that Mr. Oaks was negligently administered a drug known as heparin by employees of the Medical Center although it was known from a previous confinement at the Medical Center that Mr. Oaks was allergic to this drug").

²⁰ Dkt. 1040, pp. 18-19.

²¹ *Estate of French v. Stratford House*, 333 S.W.3d 546, 557 (Tenn. 2011).

²² *Id.*

The relationship between the Plaintiffs and the Tennessee Clinic Defendants is plainly based on the provision of health care services, not the sale of a good, as illustrated by the allegations of the Master Complaint:

- The Plaintiffs sought treatment from the Clinic Related Defendants.
- The Clinic Related Defendants and their employees, affiliates, and agents owed Plaintiffs numerous duties including, without limitation, the following: to act as reasonable and prudent healthcare providers; and to ensure that the medical treatment, including drugs, that they administered to patients, including Plaintiffs, were safe and effective.
- As part of this medical treatment, the Clinic Related Defendants administered NECC contaminated drugs, and/or NECC drugs suspected to be contaminated, to the Plaintiffs.²⁴

Even though these 43 complaints attempt to bring only product liability claims, *they still allege injury related to the provision of health care services*:

- Plaintiff received a lumbar epidural steroid injection (“ESI”) at Saint Thomas Neurosurgical. During that procedure the anesthesiologist injected 80 mg/ml [*sic*] [methylprednisolone acetate] into Mr. Barnard’s lower back...As a direct and proximate result of the contaminated ESI’s [*sic*], Mr. Barnard had to endure a lumbar puncture to test for meningitis.²⁵

Alleging that the Defendants injected a medication, causing injury to the patient fits *the exact definition of a health care liability action*. Both common sense and the straightforward language of the complaints demonstrate that the Plaintiffs allege injuries *related to the provision of health care services*.

Finally, if the Court finds that both the HCLA and PLA could apply to these 43 complaints, well-settled canons of construction direct that the more recent²⁶ and more

²³ *Hudson v. Town & Country True Value Hardware*, 666 S.W.2d 51, 53 (Tenn. 1984).

²⁴ Master Compl. ¶¶ 151-53 (emphasis added).

²⁵ *E.g., Barnard v. Ameridose, et al.*, No. 1:13-cv-12738, Compl. ¶¶ 156, 161. Nearly identical statements are included in every complaint purporting to allege only product liability.

²⁶ *Posadas v. National City Bank*, 296 U.S. 497, 503 (1936) (citing canon of construction holding that more recent statute governs conflicting earlier statute).

specific statute should apply.²⁷ Given that the HCLA is the more recent statute²⁸ that specifically governs claims against health care providers, it governs the Plaintiffs' claims, not the PLA.

B. The Plaintiffs' failure to file a certificate of good faith with their original complaints requires dismissal of those suits with prejudice.

As explained above, the HCLA applies to these 43 suits. Thus, the Court must apply the HCLA's certificate of good faith requirement to the Plaintiffs' complaints.

To save these complaints from dismissal, the PSC puts forth the convoluted argument that, even if the Court finds the HCLA applies, no certificate of good faith is necessary because product liability claims do not require expert testimony and do not require proof of negligence.²⁹

This contention ignores three important points: (1) the Plaintiffs' claims are health care liability actions governed by the HCLA, "regardless of any other claims, causes of action, or theories of liability alleged in the complaint;"³⁰ (2) even if the Plaintiffs could somehow bring a product liability claim under the HCLA, the HCLA expressly prohibits

²⁷ *Long Island Care at Home, Ltd. v. Coke*, 127 S. Ct. 2339, 2348 (U.S. 2007) (internal citations omitted) (noting well-settled canon of statutory construction holding that more specific statutory provision trumps a conflicting general statutory provision).

²⁸ The HCLA was passed in 2011, while the PLA was passed in 1978.

²⁹ Ironically, the PSC argues that the Defendants have cited no case dismissing a product liability suit for failure to file a certificate of good faith. The reason for this dearth of precedent is obvious: Tennessee plaintiffs have not sued health care providers for product liability because Tennessee law does not permit it. The statute is clear that suits against health care providers for injury related to the provision of health care services must proceed pursuant to the HCLA.

³⁰ TENN. CODE ANN. § 29-26-101(c).

liability without proof of negligence;³¹ and (3) the Plaintiffs' product liability claims do not fit any recognized exception to the expert proof requirements of the HCLA.³²

The 43 suits subject to dismissal for failure to file a certificate of good faith fit into three categories:

1. Thirteen (13) suits in which the Plaintiff either explicitly alleges health care liability or ordinary negligence but *never* filed a certificate of good faith.³³

These Plaintiffs specifically alleged health care liability or ordinary negligence but failed to file a certificate of good faith. There is nothing to excuse failure to file a certificate of good faith with complaints that specifically allege health care liability, and the passage of the HCLA eliminated the distinction between ordinary and professional negligence (health care liability) actions against health care providers.³⁴ These suits should be dismissed with prejudice pursuant to Tenn. Code Ann. § 29-26-122(c).

³¹ TENN. CODE ANN. § 29-26-115 (“(c) In a health care liability action...there shall be no presumption of negligence on the part of the defendant.... (d) ... The jury shall be further instructed that injury alone does not raise a presumption of the defendant's negligence.”).

³² *C.f.* TENN. CODE ANN. § 29-26-115(c) (“...there shall be a rebuttable presumption that the defendant was negligent where it is shown by the proof that the instrumentality causing injury was in the defendant's (or defendants') exclusive control and that the accident or injury was one which ordinarily doesn't occur in the absence of negligence.”); *Moses v. Dirghangi*, No. W2011-02403-COA-R3-CV, 2013 WL 5519506, at *11 (Tenn. Ct. App. Oct. 3, 2013) (noting that expert proof is not required in medical battery cases) (internal citations omitted).

³³ These suits are identified in Exhibit 1. The PSC incorrectly states in its Response that all Plaintiffs have now amended their complaints to file the required certificate of good faith, but that is not the case.

³⁴ See *Parker v. Portland Nursing & Rehab*, No. M2011-02633-COA-R9-CV, 2012 WL 3776800, at *4, *5, n. 4 (Tenn. Ct. App. Aug. 30, 2012) (“[a]s Plaintiff correctly states, claims for ordinary negligence and medical malpractice are separate and distinct causes of action as discussed in *Estate of French v. Stratford House*, 333 S.W.3d 546 (Tenn. 2011)....Both parties note that the passage of the Tennessee Civil Justice Act of 2011 ended this distinction and created a new cause of action of a ‘health care liability’ claim”). The sponsoring legislator described the intent of the HCLA: “It is advantageous in the minds of some plaintiffs to keep [their lawsuit] out from under the health care provider statutes, make a cause of action look like something it isn't at its core, so you spend most of your time at the outset trying to define what the cause of action is. We're hopeful that this statute will obviate some of that and reduce some of that time and expense.” available at http://tnga.granicus.com/MediaPlayer.php?view_id=196&clip_id=4266&meta_id=81904 (discussion beginning at 1:04:00). Ordinary negligence claims against health care providers for injury related to the provision of health care services must now proceed according to the HCLA. *Parker*, No. M2011-02633-COA-R9-CV, 2012 WL 3776800, at *4, *5, n. 4. Accordingly, the Court should dismiss, with prejudice, suits where the Plaintiff alleges ordinary negligence but never filed a certificate of good faith.

2. Eighteen (18) suits in which the Plaintiff purports (by the title in the pleading) to allege only product liability but actually makes a claim for ordinary negligence, and later amended to explicitly add HCLA claims and file a certificate of good faith.³⁵

In their original complaints, these Plaintiffs allege injury related to the provision of health care services but did not file a certificate of good faith because they contend, by titling their pleading as “product liability,” they do not have to comply with the statute.

Despite contending that the complaints only allege product liability, 18 of these complaints also allege ordinary negligence. The following allegation is included in each of these 18 complaints (along with other allegations that plainly sound in negligence):

The [Tennessee Clinic Defendants] did not conduct appropriate due diligence or investigation into NECC before deciding to purchase and administer NECC compounded steroids to their patients....³⁶

This states a claim for negligence, not product liability. By stating a claim for negligence, these complaints become health care liability actions *regardless of other claims, causes of action, or theories put forth in the complaints.*³⁷ ³⁸ As health care liability actions, the Plaintiffs must file certificates of good faith.

Moreover, the failure to file a certificate of good faith cannot be cured by amendment.³⁹ The certificate must be filed with the original complaint.⁴⁰

Accordingly, these 18 suits should be dismissed with prejudice.

³⁵ These suits are identified in Exhibit 2.

³⁶ *E.g., Barnard v. Ameridose, et al.*, No. 1:13-cv-12738, Compl. ¶ 132; *Berry v. Ameridose, et al.*, No. 1:13-cv-12838, Compl. ¶ 132; *Barger v. Ameridose, et al.*, No. 1:13-cv-12619, Compl. ¶ 151.

³⁷ TENN. CODE ANN. § 29-26-101(c).

³⁸ See *supra* note 34.

³⁹ *Vaughn v. Mountain States Health Alliance*, E2012-01042-COA-R3-CV, 2013 WL 817032, at *2 (Tenn. Ct. App. March 5, 2013) *perm. app. denied* May 15, 2014.

⁴⁰ TENN. CODE ANN. § 29-26-122(c); *Vaughn*, E2012-01042-COA-R3-CV, 2013 WL 817032, at *2.

3. Twelve (12) suits where the Plaintiff purported to file a suit alleging only product liability and later amended to explicitly add HCLA claims and file a certificate of good faith.⁴¹

Like the Plaintiffs in the second category, these Plaintiffs allege injury related to the provision of health care services⁴² but failed to file a certificate of good faith. That failure cannot be cured by amendment.⁴³

These complaints should also be dismissed with prejudice.

II. The Plaintiffs' presuit notices did not include the information required by Tenn. Code Ann. § 29-26-121(a)(2).

The HCLA requires plaintiffs to send presuit notice to *all* potential defendants at least 60 days before filing a health care liability action.⁴⁴ Section 29-26-121(a)(2) sets out specific content that must be included with the presuit notice. The parties agreed to brief one global issue on the content requirements of -121:

Whether plaintiffs were required to (a) identify Barry Cadden, NECC, and other affiliated parties in the notice of intent to the clinic defendants as health care providers that would be named defendants and (b) provide a HIPAA release allowing clinic defendants to obtain records presuit from Barry Cadden, NECC, and other affiliated defendants pursuant to Tenn. Code Ann. § 29-26-121.⁴⁵

A. The HCLA required the Plaintiffs to identify NECC and the Affiliated Defendants as potential defendants in the presuit notices sent to the Tennessee Clinic Defendants.

Tenn. Code Ann. § 29-26-121(a)(1) requires presuit notice to be sent to “each health care provider that will be a named defendant at least sixty (60) days before the filing of a complaint based upon health care liability.” Tenn. Code Ann. § 29-26-121(a)(2)(D) requires the notice to identify other health care providers being sent a

⁴¹ These suits are identified in Exhibit 3.

⁴² See *supra* note 25.

⁴³ *Vaughn*, E2012-01042-COA-R3-CV, 2013 WL 817032, at *2.

⁴⁴ TENN. CODE ANN. § 29-26-121(a).

⁴⁵ Dkt. 1100-1.

notice. Thus, the notice must list all potential defendants to inform other potential defendants' presuit investigation.

The PSC does not dispute that the Plaintiffs were required to send presuit notice to the Tennessee Clinic Defendants. Likewise, the PSC does not dispute that the Plaintiffs failed to identify NECC and the Affiliated Defendants in the presuit notices sent to the Tennessee Clinic Defendants. Instead, the PSC argues that the Plaintiffs were not required to do so.

This ignores the definition of "health care provider" in the HCLA.

The definition of "health care provider" includes "[a] health care practitioner licensed, authorized, certified, registered, or regulated under any chapter of title 63...."⁴⁶ "Health care provider" also includes employees of a health care provider.⁴⁷

NECC and Barry Cadden were both licensed health care providers by the Tennessee Board of Pharmacy.⁴⁸ Glenn Chin is also a health care provider within the meaning of the HCLA as an employee of NECC. Thus, NECC, Barry Cadden, and Glenn Chin are "health care providers" that are "named defendants" in a "complaint based upon health care liability." Under the plain language of the statute, the Plaintiffs were required to send them presuit notice 60 days before suit was filed *and identify them in the presuit notices sent to the Tennessee Clinic Defendants.*

The PSC tells the Court (incorrectly) that "[t]he Tennessee Plaintiffs plead product liability claims against NECC and its affiliates, not health care liability actions."⁴⁹

⁴⁶ TENN. CODE ANN. § 29-26-101(a)(2)(A).

⁴⁷ TENN. CODE ANN. § 29-26-101(a)(2)(D).

⁴⁸ Arguably, Lisa Cadden was a health practitioner "regulated" under title 63 because she was a pharmacist working at NECC, which was required to comply with Tennessee Board of Pharmacy regulations.

⁴⁹ Dkt. 1116, p. 3.

However, the claims against the Affiliated Defendants are almost universally pled as “Negligence,” “Negligence *Per Se*,” “Negligent Supervision,” and “Public Nuisance,”⁵⁰ not “Product Liability.”⁵¹

The HCLA subsumed all negligence claims against health care providers for injury related to the provision of health care services under the definition of “health care liability.”⁵² This includes the ordinary negligence claims against the Affiliated Defendants. Even the Plaintiffs’ negligence *per se* and public nuisance claims are based on a violation of a Board of Pharmacy regulation, 247 CMR 6.02(1). Thus, the claims against the Affiliated health care provider Defendants are actually HCLA claims.

Regardless, the trigger for the presuit notice requirement is not that the plaintiff will actually sue each health care provider for health care liability. It is that the health care provider will be (1) a “named defendant,” (2) in a complaint alleging health care liability.⁵³ Here, both conditions are satisfied because the Affiliated Defendants (1) are named defendants, and (2) the Plaintiffs specifically allege health care liability against the Tennessee Clinic Defendants.

Because these two conditions are met, the Plaintiffs were required to identify NECC and the other Affiliated Defendants in the presuit notice to the Tennessee Clinic Defendants.

⁵⁰ *E.g., Parman v. Ameridose, et al.*, No. 1:13-cv-12433-RWZ, Compl. Counts III-VI.

⁵¹ Even if the Plaintiffs had actually pled product liability claims against NECC and the Affiliated Defendants, the HCLA, not the PLA, is still the governing statute. The Plaintiffs’ alleged injuries are “related to” health care services provided by NECC and its employees. The HCLA defines “health care services” to include care provided by “pharmacists, pharmacy interns, or pharmacy technicians under the supervision of a pharmacist....” TENN. CODE ANN. § 29-26-101(b). NECC and Barry Cadden were both licensed by the Tennessee Board of Pharmacy. Regardless, in most if not all the complaints against the Tennessee Clinic Defendants, the Plaintiffs do not even style their claims against the Affiliated Defendants as product liability claims, let alone properly plead them.

⁵² See *supra* note 34.

⁵³ TENN. CODE ANN. § 29-26-121(a)(1).

The PSC contends NECC and the Affiliated Defendants' unilateral waiver of presuit notice eliminated the need to identify them in the presuit notices sent to other defendants. The PSC argues that, because NECC and the Affiliated Defendants are not "being sent a notice," those defendants did not need to be identified in the notices sent to other defendants, including the Tennessee Clinic Defendants.

This argument ignores the statute's primary purpose: enabling defendants to perform a presuit evaluation of the suit and to facilitate presuit settlement.^{54 55} Knowing the identities of other potential defendants in a suit is crucial to presuit evaluation of claims. Further, § 29-26-121 does not permit one potential defendant to waive the requirement for another potential defendant. The Tennessee Clinic Defendants did not waive their statutory right to know which other defendants would be named in the suits against them.

B. The Plaintiffs' failure to identify NECC and the Affiliated Defendants in the presuit notices sent to the Tennessee Clinic Defendants warrants dismissal.

Next, the PSC, argues that the failure to identify NECC and the Affiliated Defendants does not warrant dismissal because the Tennessee Clinic Defendants are required to, but cannot, demonstrate prejudice. However, the Defendants *were* prejudiced, and prejudice is only half of the relevant inquiry.

The HCLA sets out certain, specific content that must be included in the presuit notice sent to potential defendants.⁵⁶ The Tennessee Supreme Court held in *Stevens*

⁵⁴ Section 29-26-121(a)(2)(E) requires plaintiffs to send, with the presuit notice, a HIPAA-compliant medical authorization enabling potential defendants to obtain the plaintiff's medical records from other potential defendants.

⁵⁵ *Stevens*, 418 S.W.3d at 560 (holding that dismissal is proper remedy for failure to comply with § 29-26-121).

⁵⁶ TENN. CODE ANN. § 29-26-121(a)(2).

that plaintiffs must “substantially comply” with each of the content requirements.⁵⁷ In evaluating substantial compliance, a court must “consider the extent and significance of the plaintiff’s errors and omissions and whether the defendant was prejudiced by the Plaintiff’s noncompliance.”⁵⁸

Here, both factors weigh in favor of dismissal.

NECC and the Affiliated Defendants are key defendants in these cases. The vast majority of Tennessee Plaintiffs *entirely omitted them* from the presuit notice sent to the Tennessee Clinic Defendants. It is difficult to conceive of a more significant or extensive deviation from the requirements of these particular provisions of Tenn. Code Ann. § 29-26-121. The first factor in the “substantial compliance” analysis weighs in favor of dismissal.

The PSC argues that the Tennessee Clinic Defendants cannot demonstrate prejudice from this violation of § 29-26-121, given that there were no medical records to obtain from NECC and the Affiliated Defendants.⁵⁹ But, this assumes that the inability to obtain medical records is the only way the Tennessee Clinic Defendants could have been prejudiced. The prejudice here is much easier to identify (and more significant).

First, the suits against the Tennessee Clinic Defendants are much different if NECC and the Affiliated Defendants are co-defendants as opposed to nonparties, and omitting them from the presuit notices indicated they would be not be named as defendants. As named defendants, the burden of proving the fault of NECC and the

⁵⁷ *Stevens*, 418 S.W.3d at 556 (dismissing suit for failure to substantially comply with § 29-26-121(a)(2)(E)); *Thurmond v. Mid-Cumberland Infectious Disease Consultants*, --- S.W.3d ---, No. M2012-02270-SC-R11-CV, 2014 WL 1632183 (Tenn. April 24, 2014) (analyzing whether plaintiff substantially complied with § 29-26-121(a)(4)).

⁵⁸ *Id.* (emphasis added).

⁵⁹ See *supra* note 54.

Affiliated Defendants would be borne chiefly by the Plaintiffs. The Tennessee Clinic Defendants could rely on this proof when asserting comparative fault. Additionally, NECC and the Affiliated Defendants would likely have contested the allegations against them, possibly reducing the fault apportioned to them by the jury.

On the other hand, if NECC and the Affiliated Defendants are nonparties, the Tennessee Clinic Defendants bear the burden of proving NECC and the Affiliated Defendants' fault to establish comparative fault. Further, at trial, no party would present a defense to proof of that fault. This dynamic dramatically affects the presuit evaluation of these cases due to the time and expense necessary to discover and prove the fault of these entities and its potential effect on valuation of the cases.

Second, the venue of these suits changed with the addition of the Affiliated Defendants. Four plaintiffs filed suit in Tennessee state court against a subset of the Tennessee Clinic Defendants (Saint Thomas Outpatient Neurosurgical Center and Howell Allen) in early 2013 without naming NECC or the Affiliated Defendants.⁶⁰ Pursuant to Judge Saylor's Order on the Trustee's Motion to Transfer, those suits were not subject to transfer to the MDL.⁶¹ Without the complexity of the MDL, they progressed quickly through substantial written discovery toward trial (until the plaintiffs abruptly voluntarily dismissed them when faced with the Defendants' motion to dismiss their product liability claims).

Given that NECC and the Affiliated Defendants were not named in the vast majority of the presuit notices, the Tennessee Clinic Defendants were led to believe that

⁶⁰ *Reed v. STOPNC, et al.*, Case No. 13C417, *May v. STOPNC, et al.*, Case No. 13C606, *Parman v. STOPNC, et al.*, Case No. 13C1005, and *Neely v. STOPNC, et al.*, Case No. 13C1876, all formerly pending in the Fifth Circuit Court for Davidson County, Tennessee.

⁶¹ Dkt. 170, p. 31.

those suits would be filed in state court, which would likely have resulted in sooner trials, and litigation much different than a complex MDL in a venue hundreds of miles from Tennessee.⁶² This incorrect belief regarding the likely venue impacted the Tennessee Clinic Defendants' presuit evaluation of the suits against them and resulted in prejudice.

Accordingly, the Tennessee Clinic Defendants respectfully request that the Court dismiss all suits where the Plaintiff failed to identify the Affiliated Defendant health care providers in the presuit notice sent to the Tennessee Clinic Defendants.⁶³

C. Case-specific hearings on substantial compliance are unnecessary.

The PSC repeatedly argues that a case-specific hearing on substantial compliance must be conducted before any suit can be dismissed for failure to comply with Tenn. Code Ann. § 29-26-121. In the context of the current Motion, substantial compliance is only relevant to whether the Plaintiffs were required to identify NECC and the Affiliated Defendants in the presuit notices sent to the Tennessee Clinic Defendants.⁶⁴ The PSC already agreed that this is a "global" issue in the extensive negotiations that occurred before the parties agreed to the current briefing schedule. Indeed, the Court can and should decide it as such.

⁶² The Defendants' belief that these cases would be filed in state court was bolstered by the favorable reaction of Tennessee Plaintiffs' attorneys to Judge Saylor's ruling on the Trustee's Motion to Transfer. See "Meningitis lawsuits will stay in state court for now," *The Tennessean* (June 2, 2013) (quoting several Tennessee Plaintiffs' attorneys) available at <http://archive.tennessean.com/article/20130602/NEWS07/305310160/Meningitis-lawsuits-will-stay-state-now>.

⁶³ These suits are identified in Exhibit 4.

⁶⁴ See *Myers v. AMISUB (SFH), Inc.*, 382 S.W.3d 300, 309 (Tenn. 2012) (holding that the HCLA's requirement that certificate of good faith be filed with the complaint is subject to strict, not substantial, compliance).

Here, both parts of the *Stevens* “substantial compliance” analysis can be evaluated in global fashion. The extent and significance of the omission is the same for every Plaintiff who failed to identify these entities in the presuit notice, just like the resulting prejudice to the Tennessee Clinic Defendants. The PSC has given no explanation for how or why a case-specific hearing is necessary or will even be helpful to the Court. The Court need not conduct any such hearings prior to resolving this global issue pursuant to the parties’ agreed briefing schedule.

III. The HCLA does not conflict with FRCP 8.

In a feeble attempt to save these suits from dismissal, the PSC claims the HCLA’s 60-day presuit notice requirement and the PLA’s statute of limitations created a “catch-22” that made it impossible for the Plaintiffs to comply with both statutes. The PSC argues that this restricted the Plaintiffs’ “absolute right” to plead claims in the alternative pursuant to FRCP 8.

However, there is no conflict between FRCP 8 and the certificate of good faith requirement. Nothing in the HCLA prohibited the Plaintiffs from filing the certificate of good faith prior to the expiration of the 60-day notice period. At least one Plaintiff did just that.⁶⁵

Likewise, the Court need only look at the numerous suits filed by Tennessee Plaintiffs that comply with both the HCLA’s 60-day presuit notice requirement and the PLA’s statute of limitations to see the fallacy of the PSC’s argument. Indeed, 112 out of 142 Tennessee Plaintiffs complied with the HCLA’s presuit notice requirements before

⁶⁵ *Foster v. Ameridose, et al.*, No. 1:13-cv-12686, Compl. ¶¶ 177-79, Ex. B (acknowledging that 60 days had not elapsed from the sending of presuit notice but filing certificate of good faith anyway).

filing their product liability claims. The Plaintiffs who failed to do so could have remedied this problem simply by sending their presuit notices earlier.

Simply put, there was no catch-22 or conflict with FRCP 8.⁶⁶

IV. The Tennessee Clinic Defendants will not address issues beyond those set forth in the parties' agreed briefing schedule.

The relevant history to briefing on the current Motion is:

1. At the December 2013 status conference, the PSC asked Judge Saylor to order Tennessee defendants to identify suits with presuit notice issues.⁶⁷ Judge Saylor ordered defendants to identify presuit notice issues by filing a motion to dismiss that identified the case name and civil action number and provided "a brief description of the alleged problem/insufficiency in satisfying state-law presuit filing requirements."⁶⁸
2. In response to the order, the Defendants complied by filing the instant Motion to Dismiss at Dkt. 770 and attached as an exhibit a table identifying the cases and the deficiencies.⁶⁹ Because the PSC claimed that there was not enough detail in the table, the Tennessee Clinic Defendants filed their Memorandum of Law, fully setting forth the basis for each deficiency.⁷⁰ This was done consistent with the briefing schedule agreed to by the PSC.⁷¹
3. Again, the PSC complained, this time asserting that some of the issues raised in the Motion to Dismiss were not truly "global" issues appropriate for briefing at this stage of the MDL.⁷² The Tennessee Clinic Defendants agreed to limit the issues to be briefed by the PSC to those issues which were truly global. *The parties then agreed on what issues were global and would be briefed*, and submitted (another) agreed briefing schedule on April 24.⁷³ The parties agreed to brief only the three issues discussed herein.

⁶⁶ See, e.g., *Clark v. Sarasota County Pub. Hosp. Bd.*, 65 F. Supp. 2d 1308, 1314 (M.D. Fla. 1998) ("nothing in the federal Constitution, statutes, or rules compels the federal court to refuse to employ the [medical malpractice presuit] screening process — the best case for the claim that Rule 8 does so is quite weak...") (quoting John H. Robinson, *The Compromise of '38 and The Federal Courts Today*, 73 N.D. L. REV. 891, 905 (1998)).

⁶⁷ Hr'g Tr. 35:20-36:8 (Dec. 12, 2013 status conference).

⁶⁸ Dkt. 723.

⁶⁹ The Defendants did not initially file a brief in support because it was not required by Judge Saylor's Order.

⁷⁰ Dkt. 898.

⁷¹ The briefing schedule is at Dkt. 845.

⁷² Letter from PSC attached as Exhibit 5.

⁷³ Dkt. 1100-1.

4. Just two weeks later, the PSC filed its Opposition to the Tennessee Clinic Defendants' Motion to Dismiss. In its Opposition, the PSC unilaterally added an additional issue to the parties' agreed briefing schedule:

Whether the claims of certain plaintiffs should be dismissed because their middle names were not included in presuit notice letters notifying the Defendants of plaintiffs' intent to file suit.⁷⁴

The PSC cherry-picked this particular issue to make the Tennessee Clinic Defendants seem unreasonable in moving for dismissal on such a technical issue. The Tennessee Clinic Defendants never seriously believed that this deficiency alone was sufficient to warrant dismissal under the substantial compliance analysis, only that the Court should consider this deficiency in light of the half dozen or so other deficiencies when evaluating "the extent and significance of the plaintiff's errors and omissions," as required by *Stevens*.⁷⁵

Regardless, the Tennessee Clinic Defendants will not address issues presented to the Court outside the agreed-upon briefing arrangement, and particularly not case-specific issues unilaterally cherry-picked by the PSC.⁷⁶ This is a waste of the parties' and Court's time.

Conclusion

For the foregoing reasons, the Tennessee Clinic Defendants respectfully request an Order:

1. Dismissing, with prejudice, all cases where the Plaintiff failed to file a certificate of good faith with the original complaint; and⁷⁷
2. Dismissing all cases where the Plaintiff failed to identify NECC and the Affiliated Defendants in the presuit notice sent to the Tennessee Clinic Defendants.⁷⁸

⁷⁴ Dkt. 1116, p. 2.

⁷⁵ *Stevens*, 418 S.W.3d at 556.

⁷⁶ The PSC even explicitly identified this as a case-specific issue. See Exhibit 5, p. 2.

⁷⁷ Suits identified in Exhibits 1, 2, and 3.

⁷⁸ Suits identified in Exhibit 4.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 9th day of June, 2014.

/s/ Chris Tardio

Chris Tardio

⁷⁹ Admitted pursuant to MDL Order No. 1.

⁸⁰ Admitted *pro hac vice*.